

Message

From: Lund, Lisa [Lund.Lisa@epa.gov]
Sent: 4/1/2015 6:35:27 PM
To: Vizard, Elizabeth [Vizard.Elizabeth@epa.gov]; Liem, Francisca [Liem.Francisca@epa.gov]
CC: Duffy, Rick [Duffy.Rick@epa.gov]; Smidinger, Betsy [Smidinger.Betsy@epa.gov]
Subject: FW: e-mail response

Frances, please send this version of response to Mr. Wnorowski. Thanks

From: Wilson, Shari
Sent: Wednesday, April 01, 2015 1:47 PM
To: Lund, Lisa
Subject: e-mail response

Lisa – Cynthia sent this to me. Looks fine to me. Thanks.

Draft Response From Francisca Liem to Incoming Email:

Dear Mr. Wnorowski,

Your email to Jim Jones has been forwarded to me for response. As Jim Jones indicated in his email to you, I am the Chief of the Good Laboratory Practice (GLP) Program Section in the Office of Enforcement and Compliance Assurance. As such, I sincerely appreciate receiving feedback from members of the GLP community and recognize the issues and concerns raised in your email.

I want to assure you that EPA's goal is to maintain and operate a GLP Program that meets OECD membership requirements and promotes a strong United States economy by conducting rigorous inspections and actively monitoring compliance with GLP regulations. As currently written, neither the Federal Insecticide, Fungicide and Rodenticide Act nor the Good Laboratory Practice regulations authorize the EPA to certify GLP laboratories in the US. Instead, studies that are submitted to EPA in support of registration applications must be conducted in accordance with the GLP regulations. EPA's current inspection program, without certification requirements, is accepted by OECD, allowing the U.S. to actively participate in the Mutual Acceptance of Data program with other membership countries.

If you would like to discuss your concerns or if you have any questions about EPA's GLP program, please contact me at the number below.

Sincerely,
Francisca Liem, Chief
Good Laboratory Practice Program Section
Office of Compliance
Office of Enforcement and Compliance Assurance
(202) 564-4148

Background-Incoming email chain:

From: Jones, Jim
Sent: Monday, March 16, 2015 2:51 PM
To: Gary Wnorowski
Cc: Liem, Francisca; Giles-AA, Cynthia
Subject: RE: GLP Certification

Gary, I am forwarding your message to my colleague in the Office of Enforcement and Compliance Assurance, Frances Liem. She has responsibility for the issue you have raised. Thanks. Jim

From: Gary Wnorowski [<mailto:GaryWnorowski@productsafetylabs.com>]

Sent: Monday, March 16, 2015 10:29 AM

To: Jones, Jim

Subject: RE: GLP Certification

Jim

I never heard back from you about this. Can we please schedule a time to speak this week?

Gary

From: Gary Wnorowski

Sent: Saturday, February 28, 2015 6:55 AM

To: 'Jones, Jim@Epa.gov'

Subject: GLP Certification

Jim

I manage a contract lab that specializes in the conduct of toxicology and chemistry studies on pesticides for submission to global regulatory authorities for registration. We continue to be put at a significant competitive disadvantage in the industry because of EPA's resistance to issuing GLP certificates like every other OECD nation. Several times in the last few months, we have lost projects to laboratories in other countries because of this issue. Just this morning, our Director of Analytical Services received the following email from a Chinese client.

Dear Peter,

Good day!

I am very sorry to tell you that we would not put the study of glyphosate ammonium in your lab.

Because the Korea client tell us that the Korea Authority only accept the report with GLP certificate when evaluation. We decide to choose OECD GLP Lab. Thank you very much for your work. I hope we can cooperate next time.

Yours sincerely,

Julie Wang

Market & Registration Division

I have been with Product Safety Labs for over 25 years and have grown incredibly frustrated over this issue. I would like to know if you could be available for a short discussion by phone so that I could understand the agencies position on this issue and discuss possible ways to address it.

Best regards

Gary Wnorowski

President

Product Safety Labs (www.productsafetylabs.com)

2394 Highway 130

Dayton, NJ 08810

Office 732-438-5100 ext 4208

Mobile 732-859-6756

<mailto:garywnorowski@productsafetylabs.com>

- Repeated Dose Toxicology
- Reproductive/Developmental Toxicology
- Genetic Toxicology
- Environmental Toxicology

- Product Chemistry
- GLP Analytical Chemistry
- Antimicrobial Efficacy

Shari T. Wilson

Deputy Assistant Administrator, Office of Enforcement and Compliance Assurance

U. S. EPA

WJC South, Room 3213

1200 Pennsylvania Avenue, N.W.

Washington D.C. 20460

202-564-2440 (main)

202-564-8029 (direct)

202-760-0467 (cell)

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